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Title: POLYACRYLAMIDE HYDROGEL AND ITS USE AS AN ENDOPROSTHESIS

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## In the Claims:

Please amend the claims as follows:

1. (Currently Amended) A hydrogel <u>suitable for use as an endoprosthesis, the hydrogel comprising:</u>

a polyacrylamide which includes a polymer of acrylamide cross-linked with methylene bis-acrylamide, wherein the acrylamide and methylene bis-acrylamide are combined in a molar ratio of 150:1 to 1000:1 and wherein the hydrogel comprises about 0.5 to less than 3.5% of the polyacrylamide by weight, based on the total weight of the hydrogel, and

water or an aqueous solution,

wherein the hydrogel comprises less than 50 ppm of acrylamide and methylene bisacrylamide monomers; and wherein the hydrogel has an elasticity module from about 10 to 700 Pa and a complex viscosity from about 2 to 90 Pas said hydrogel obtainable by combining acrylamide and methylene bis acrylamide, under conditions of radical initiation, and washing with pyrogen free water or saline solution; said hydrogel being biocompatible.

- 2. (Currently Amended) A hydrogel <u>according to claim 1 wherein the hydrogel</u> <u>comprises comprising i) less than 3.5% polyacrylamide by weight, based on the total weight of the hydrogel, cross linked with methylene bis acrylamide and ii) at least 95% <u>by weight</u> <u>pyrogen free</u> water or <u>saline aqueous solution based on the total weight of the hydrogel</u>.</u>
  - 3. (Cancelled)
  - 4. (Cancelled)
- 5. (Currently Amended) A hydrogel according to claim  $\underline{1}[[2]]$ , comprising at least  $\underline{1}$ % [[0.5%]] by weight of the polyacrylamide, based on the total weight of the hydrogel.

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- 6. (Cancelled)
- 7. (Currently Amended) A hydrogel according to claim  $\underline{1}$  [[2]], which has  $\underline{a}$  complex viscosity from about  $\underline{5}$  [[2]] to  $\underline{80}$  [[90]] Pas.
- 8. (Currently Amended) A hydrogel according to claim  $\underline{1}$  [[2]], which has  $\underline{an}$  elasticity module of not less than  $\underline{20}$  [[10]] Pa.
- 9. (Currently Amended) A hydrogel according to claim  $\underline{1}$  [[2]], which has  $\underline{an}$  elasticity module from about  $\underline{35}$  [[10]] to  $\underline{480}$  [[700]] Pa.
- 10. (Currently Amended) A hydrogel according to claim 1 [[2]], which includes the eross-linked polyacrylamide to such a degree so as to have an efficient has a cross-linking density of about 0.2 to 0.5%.
- 11. (Previously Presented) A hydrogel according to claim 1, wherein the acrylamide and methylene bis-acrylamide are combined in the molar ratio of from 175:1 to 800:1.
- 12. (Currently Amended) A hydrogel according to claim 1 [[3]], which is suitable for wherein the an implantable endoprosthesis comprises a silicone based envelope housing the hydrogel.
- 13. (Withdrawn) An implantable or injectable endoprosthesis comprising a hydrogel as defined in claim 2.
- 14. (Withdrawn) An endoprosthesis according to claim 13, further comprising a silicone-based envelope housing the hydrogel.
  - 15. (Withdrawn) An endoprosthesis according to claim 13 further comprising cells.
- 16. (Withdrawn) A method for the preparation of a hydrogel comprising the steps of combining acrylamide and methylene bis-acrylamide, under conditions of radical initiation, and

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washing with pyrogen-free water so as to give less than 3.5% by weight polyacrylamide, based on the total weight of the polyacrylamide.

- 17. (Withdrawn) The method according to claim 16, wherein the hydrogel comprises at least 1.5% polyacrylamide by weight, based on the total weight of the hydrogel.
- 18. (Withdrawn) A method according to claim 16, wherein the washing step comprises swelling the product for 50-250 hours, more typically for 70 to 200 hours.
- 19. (Withdrawn) The method according to claim 16, wherein the washing step comprises swelling the product of the radical initiation step until the elasticity module is from about 10 to 700 Pa.
- 20. (Withdrawn) The method according to claim 16, wherein the washing step comprises swelling the product for 50 to 250 hours.
- 21. (Withdrawn) The method according to claim 16, wherein the combining is in a ratio of acrylamide and methylene bis-acrylamide of about 150:1 to 1000:1
- 22. (Withdrawn) The method according to claim 21, wherein the ratio of acrylamide to methylene bis-acrylamide is about 175:1 to 800:1.
- 23. (Withdrawn) A method of treatment of a cosmetic or functional defect with an injectable or implantable biocompatible endoprosthesis comprising:
- a) preparing a polyacrylamide hydrogel, said polyacrylamide hydrogel comprising less than 3.5% by weight of polyacrylamide and said polyacrylamide being cross-linked with methylene bis-acrylamide,
- b) injecting or implanting a sufficient amount of said polyacrylamide hydrogel into a region of the body affected by a cosmetic or functional defect.

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- 24. (Withdrawn) The method of treatment according to claim 23, wherein the polyacrylamide hydrogel comprises at least 0.5% polyacrylamide by weight, based on the total mass of the hydrogel.
- 25. (Withdrawn) The method according to claim 23, wherein the preparation of the polyacrylamide hydrogel is according to the method defined in claim 16.
- 26. (Withdrawn) The method according to claim 23, wherein the endoprosthesis is used for mammoplastic reconstruction or augmentation, treating reflux oesophagitis, body contouring, or penis enlargement.
- 27. (Withdrawn) The method according to claim 26, wherein the endoprosthesis for mammoplastic reconstruction or augmentation is injectable or implantable.
- 28. (Withdrawn) The method according to claim 26, wherein the hydrogel comprises less than 1.6% polyacrylamide by weight, based on the total weight of the hydrogel, and wherein the endoprosthesis for mammoplastic reconstruction is implantable, said endoprosthesis further comprising a silicone-based envelope.
- 29. (Withdrawn) The method according to claim 23, wherein the polyacrylamide hydrogel comprises at least 1% by weight polyacrylamide, based on the total weight of the hydrogel.
- 30. (Withdrawn) A method of cosmetically altering a mammalian breast or of performing a partial or total mammoplastic reconstruction on a woman comprising implanting a polyacrylamide hydrogel endoprosthesis; wherein said polyacrylamide hydrogel endoprosthesis comprises: i) more than 9.5% polyacrylamide by weight, based on the total weight of the hydrogel, and ii) at least 75% pyrogen-free water or saline solution.
- 31. (Withdrawn) The method according to claim 30, wherein the polyacrylamide hydrogel endoprosthesis comprises less than 25% by weight polyacrylamide, based on the total weight of the hydrogel.

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32. (Withdrawn) The method according to claim 30, wherein the endoprosthesis further comprises a silicon-based envelope.

- 33. (Withdrawn) A method according to claim 23 comprising augmenting the size of a penis comprising the administration to the penis of a polyacrylamide hydrogel, wherein the polyacrylamide hydrogel comprises less than 3.5% polyacrylamide by weight, based on the total weight of the hydrogel.
- 34. (Withdrawn) The method according to claim 33, wherein the polyacrylamide hydrogel further comprises at least 95% pyrogen-free water or saline solution.
- 35. (Withdrawn) The method according to claim 33, wherein the administration is by means of injection into a cavernous tissue.
- 36. (Withdrawn) A method of augmenting the size of a penis comprising the implantation of a polyacrylamide hydrogel endoprosthesis wherein the polyacrylamide hydrogel endoprosthesis comprises i) more than 9.5% polyacrylamide by weight, and ii) pyrogen-free water or saline solution.
- 37. (Withdrawn) The method according to claim 36, wherein the polyacrylamide hydrogel endoprosthesis has a complex viscosity of at least 10 Pa s.
- 38. (Withdrawn) A method of cosmetically altering a mammalian body (body contouring) comprising implanting a polyacrylamide hydrogel endoprosthesis, wherein the polyacrylamide hydrogel endoprosthesis comprises i) more than 9.5% polyacrylamide by weight, based on the total weight of the hydrogel, and ii) pyrogen-free water or saline solution.
- 39. (Withdrawn) A method for treating (reflux) oesophagitis comprising implanting or injecting a polyacrylamide hydrogel endoprosthesis wherein the hydrogel comprises more than 6% polyacrylamide by weight, based on the total weight of the hydrogel.

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40. (Withdrawn) The method according to claim 23 for treating (reflux) oesophagitis by implanting or injecting an endoprosthesis wherein the hydrogel comprises less than 3.5% polyacrylamide by weight, based on the total weight of the hydrogel.

- 41. (Cancelled)
- 42. (Withdrawn) An endoprosthesis according to claim 15, wherein the cells are stem cells.
- 43. (Withdrawn) An endoprosthesis according to claim 15, wherein the cells are used for cellular engraftment.
- 44. (New) A hydrogel according to claim 1, which is suitable for use as an injectable endoprosthesis.
- 45. (New) A hydrogel according to claim 1, wherein the complex viscosity is from 6 to 40 Pas.
- 46. (New) A hydrogel according claim 12, wherein the implantable endoprosthesis comprises a silicone-based envelope housing the hydrogel.
- 47. (New) A hydrogel according to claim 1 further comprising cells for cellular engraftment.